

REMARKS

Claim Status

Claims 14-18 and 29 are pending and should be examined. No new matter has been added.

Examiner Interview Summary

Applicants thank Examiner Pak for helpful discussions during a telephone interview conducted on November 3, 2005. Applicants and Examiner Pak discussed the priority objection and the Section 112 and 103 rejections of record.

As discussed during the interview, the present application properly claims priority to U.S. Application No. 09/448,755. Because the '755 application at page 9, lines 18-28, discloses a composition comprising a thioredoxin protein linked to an oleosin, Examiner Pak agreed to reconsider the rejection.

Following a consideration of the Section 112 rejections, Applicants proposed revising the claims to clarify that the intact oil bodies are substantially intact, as defined in the specification. Examiner Pak agreed to withdraw the Section 112 rejections in view of Applicants' present amendment.

In response to the Section 103 rejections of record, Applicants noted the lack of evidence in the record that one of ordinary skill would have been motivated to combine Moloney *et al.*, Wieleś *et al.*, and Vouloury *et al.* Even if there were such evidence, moreover, the resultant combination, as noted during the interview, would not render the presently claimed invention obvious, within the meaning of Section 103. In particular, Applicants underscored the fact that the cited references do not teach a method for emulsifying a thioredoxin fusion protein having substantially intact oil bodies. While Examiner Pak agreed to revisit the art of record, she indicated that further searches are necessary. Accordingly, Applicants agreed to file the present RCE.

Priority

The PTO alleges that “Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120.” Final Office Action, pages 2-3. Specifically, the PTO alleges the “755 application does not disclose a method of preparing an emulsion formulation by using cells transformed with polynucleotides encoding a fusion protein.” *Id.* Applicants respectfully traverse this objection.

As explained during the recent Examiner Interview, the ‘755 application at page 9, lines 18-28, discloses a composition comprising a thioredoxin protein linked to an oleosin. Examiner Pak agreed to reconsider this rejection.

Rejections under 35 U.S.C. § 112 (indefiniteness)

Claims 14-18 and 29 are rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness because, according to the Examiner, “intact oil bodies” is unclear. Final Office Action, pages 3-4. Pursuant to discussion at the recent interview, Applicants have amended the claims to clarify that the oil bodies are “substantially intact oil bodies.” Support for this amendment may be found in the specification, for example, at page 12, lines 12-17. Examiner Pak indicated that such amendment would avoid her concerns, and therefore, Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 112 (written description)

Claims 14-18 and 29 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Final Office Action, pages 4-5. Specifically, the PTO alleges “obtaining oil bodies derived from recombinant cells was not described.” Additionally, the PTO alleges that the as-filed specification fails to disclose “how intact oil bodies are separated from non intact oil bodies.” As discussed during the interview, Applicants respectfully traverse the grounds for these rejections.

The as-filed specification discloses at least one method for obtaining oil bodies derived from recombinant cells. For instance, see specification at page 6, lines 15-26, and original claim 14. The specification also makes clear that the present invention produces intact oil bodies and not destroyed (*i.e.* “non-intact”) oil bodies. Applicants have amended the claim language to clarify that the oil bodies are “substantially intact oil bodies.” Support for this amendment may be found in the specification, for example, at page 12, lines 12-17. Because the present invention produces “substantially intact oil bodies,” the specification need not describe a process for separating intact oil bodies from non-intact oil bodies. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 14-16, 18, and 29 are rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Moloney *et al.*, Wielse *et al.*, and Voultoury *et al.* Final Office Action, pages 6-9. Applicants respectfully traverse this rejection.

For a proper combination of references, there must be some teaching or suggestion to that end in the prior art. *See, e.g.*, MPEP § 2142. Thus, the mere fact that references could be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. MPEP § 2143.01. None of Moloney *et al.*, Wielse *et al.*, and Voultoury *et al.* provides any suggestion that would have prompted the skilled artisan to have combined these publications in the manner posited by the PTO.

Even were there a suggestion that implicated such a combination, the combined teachings would not result in the claimed method. To establish a *prima facie* obviousness, all of the claim recitations must be taught or suggested by the prior art. MPEP § 2143.03.

The PTO alleges that Moloney *et al.* teaches a method of making a chimeric polynucleotide and Wieles *et al.* discloses polynucleotides encoding a thioredoxin and thioredoxin reductase. Final Office Action, page 7. As the PTO admits, however, “Moloney *et al.* and Wieles *et al.* fail to disclose formulating an emulsion formulation comprising a fusion protein comprising a thioredoxin or thioredoxin reductase.” Final Office Action, pages

8-9. Therefore, the PTO relies on Voultoury *et al.* to remedy the deficiencies of Moloney *et al.* and Wieles *et al.* While the PTO alleges Voultoury *et al.* discloses a method for formulating an emulsion, Voultoury *et al.*, alone or in combination with Moloney *et al.* and Wieles *et al.*, would not render the present invention obvious because Voultoury *et al.* discloses a method by “lysing or disruption of cells comprising the fusion protein.” Final Office Action, page 9. That is, the method of Voultoury *et al.* produces crushed or destroyed oil bodies and therefore could not provide a method for emulsifying a thioredoxin fusion protein having substantially intact oil bodies. Accordingly, the cited combination of references does not disclose all elements of the claims and, hence, does not establish a *prima facie* case under Section 103. For at least this reason, the rejection is improper and should be withdrawn.

Claims 17 is rejected over Moloney *et al.*, Wielse *et al.*, and Voultoury *et al.* as applied to claims 14-16, 18 and 29 above, and further in view of Hildebrand *et al.* Final Office Action, page 9. Applicants respectfully traverse this rejection.

As discussed above, neither Moloney *et al.*, Wielse *et al.*, nor Voultoury *et al.* teaches all of the elements of the claimed invention. The PTO’s reliance on Hildebrand *et al.*, to remedy the deficiencies of Moloney *et al.*, Wielse *et al.*, or Voultoury *et al.*, is misplaced, however. According to the PTO, Hildebrand *et al.*, discloses a method of expressing heterologous proteins in safflower cells, but does not disclose a method for emulsifying an oil body. Final Office Action, page 10. Accordingly, the cited references would not render the present invention obvious and the rejection should be withdrawn.

CONCLUSION

As the above-presented remarks address and avoid each rejection presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested. No new matter has been added.

If there are any questions concerning this application, the examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

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By 

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